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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,293	12/31/2003	Sangeeta N. Bhatia	MITY-001CNRCE2	9194

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EXAMINER

TENTONI, LEO B

ART UNIT	PAPER NUMBER
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1742

MAIL DATE	DELIVERY MODE
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04/18/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,293	Applicant(s) BHATIA ET AL.	
	Examiner Leo B. Tentoni	Art Unit 1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,31,34, 38-46, 48, 49, 53-61 and 63-79 is/are pending in the application.
- 4a) Of the above claim(s) 39-44 and 54-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,34,38,45,46,48,49,53,60,61 and 63-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 March 2011 has been entered.

Election/Restrictions

2. Claims 39-44 and 54-59 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 20 April 2007.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a),

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the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 30, 34, 38, 45, 46, 48, 49, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1).

Weiss et al (see the entire document, in particular, col. 1, line 15 to col. 2, line 18; col. 4, line 59 to col. 5, line 8; col. 6, lines 1-51; col. 8, line 31 to col. 9, line 46; Examples) teaches a layered polymer scaffold including two or more assembled polymer membranes, wherein the scaffold has a thickness of about one (1) millimeter and each membrane has a surface of varying topology including at least one organized feature with at least one dimension of about 25 to 250 microns. Weiss et al teaches that the scaffold is made of a polymer, but Weiss et al does not explicitly teach that the polymer is a synthetic biopolymer. Kale et al (see the entire document, in particular, paragraphs [0112] - [0116]) teaches a polymer scaffold made of a synthetic biopolymer, and it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to use a synthetic biopolymer for the scaffold of Weiss et al in view of Kale et al in order to provide a scaffold for use in the repair or replacement of tissue. Furthermore, the substitution of one known material (i.e., synthetic biopolymer of Kale et al) for another known material (i.e., polymer of Weiss et al) would have yielded predictable results (i.e., a scaffold) to one of ordinary skill in the art at the time the invention was made.

6. Claims 31, 53, 60, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1).

Weiss et al (see the entire document, in particular, col. 1, line 15 to col. 2, line 18; col. 4, line 59 to col. 5, line 8; col. 6, lines 1-51; col. 8, line 31 to col. 9, line 46; Examples) teaches a polymer scaffold including at least one membrane, wherein the scaffold has a thickness of about one (1) millimeter and each membrane has a surface of varying topology including at least one organized feature with at least one dimension of about 25 to 250 microns. Weiss et al teaches that the scaffold is made of a polymer, but Weiss et al does not explicitly teach that the polymer is a synthetic biopolymer. Kale et al (see the entire document, in particular, paragraphs [0112] - [0116]) teaches a polymer scaffold made of a synthetic biopolymer, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a synthetic biopolymer for the

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scaffold of Weiss et al in view of Kale et al in order to provide a scaffold for use in the repair or replacement of tissue.

Furthermore, the substitution of one known material (i.e., synthetic biopolymer of Kale et al) for another known material (i.e., polymer of Weiss et al) would have yielded predictable results (i.e., a scaffold) to one of ordinary skill in the art at the time the invention was made.

7. Claims 61 and 67-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (U.S. Patent 6,143,293 A) in combination with Kale et al (U.S. Patent Application Publication 2002/0127711 A1) as applied to claims 31, 53, 60, 63 and 66 above, and further in view of Masini et al (U.S. Patent Application Publication 2001/0043918 A1).

Weiss et al teaches a polymer scaffold having at least one membrane, but Weiss et al does not explicitly teach that a membrane is a mesh. Masini et al (see the entire document, in particular, paragraphs [0027] - [0029] and [0086]) teaches a polymer scaffold having a membrane which may be a mesh, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a mesh membrane in Weiss et al in view of Masini et al in order to provide a scaffold for use in the repair or replacement of tissue.

Response to Arguments

8. Applicant's arguments filed on 17 March 2011 have been fully considered but they are not persuasive.

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9. Applicant argues (pages 7-10) that Weiss et al does not teach a surface of varying topology with an organized feature formed from a biopolymer during microfabrication (emphasis added) and that Weiss et al teaches organized features (i.e., barbs) that are not formed during the process. Examiner responds that all of the pending claims are product-by-process claims, and even though product-by-process claims are limited by and defined by the process, the determination of patentability is based on the product itself and does not depend on its method of production (see MPEP §2113). Thus, any limitation in the instant claims directed to the method of production is of no significance with respect to the determination of patentability of these product-by-process claims. Weiss et al teaches organized features (i.e., product structure) and the method of production of these organized features is of no significance with respect to the determination of patentability of these product-by-process claims.

10. Applicant argues (pages 10 and 11) that there is no motivation in the Weiss et al and Kale et al references to arrive at the presently-claimed invention. Examiner responds that Weiss et al and Kale et al are directed to polymer scaffolds, and it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a synthetic biopolymer for the scaffold of Weiss et al in view of Kale et al in order to provide a scaffold for use in the repair or replacement of tissue, and the substitution of one known material (i.e.,

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synthetic biopolymer of Kale et al) for another known material (i.e., polymer of Weiss et al) would have yielded predictable results (i.e., a scaffold) to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leo B. Tentoni whose telephone number is (571) 272-1209. The examiner can normally be reached on Monday - Friday (6:30 A.M. - 3:00 P.M.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leo B. Tentoni/
Primary Examiner, Art Unit 1742